

# BIO-DETEK

INCORPORATED

K110978

MAY 13 2011

## 510(k) Summary: Rev. 2

### Submitter's Name and Address:

Bio-Detek, Inc.  
A Division of ZOLL® Medical Corporation  
525 Narragansett Park Drive  
Pawtucket, RI 02861  
Tel. (401) 729-1400

### Contact Person:

Robert Morse  
Director, Regulatory Affairs  
Tel. (866) 639-0060 x. 224

### Date Summary Prepared:

March 29, 2011

### Device Name:

**OneStep™ Pediatric Multi-function Electrode**

### Classification Name:

Electrode, Electrocardiograph, Multi-Function;  
Accessory to an External Defibrillator

### Substantial Equivalence:

The **OneStep Pediatric Electrode System** is substantially equivalent to **ZOLL ready-padz OneStep Pediatric Electrodes** that were FDA cleared on 510(k), K06559. In addition, the **OneStep Pediatric Electrode** is substantially equivalent to the originally cleared **ZOLL pedi-padz solid gel** identified on 510(k), K931787 and **padi-padz II** cleared on K033474. The intent is to show that the **OneStep Pediatric Electrodes** will assist in providing therapy for defibrillation, cardioversion, Noninvasive pacing and ECG monitoring comparable to the previously cleared devices, for use with **ZOLL Defibrillators**. All of the cleared devices are in the Regulatory Class III category.

### Description of Device:

The **OneStep pediatric Electrode System** is intended for use with **ZOLL Defibrillators**, such as, R Series M Series, and E Series for ECG monitoring, defibrillation, noninvasive pacing and cardioversion of pediatric patients in either the hospital or pre-hospital environment.

525 Narragansett Park Drive, Pawtucket, Rhode Island 02861-4323, Tel. (401) 729-1400 or (800) 225-1310, Fax (401) 729-1408

The system is comprised of a single use, disposable electrode made of conductive hydrogel with a metal conductor and adhesive perimeter suitable for coupling to patient skin during rescue and/or treatment.

Indications for Use:

Intended Use:

- Defibrillation
- Cardioversion
- Noninvasive Pacing
- ECG Monitoring

For use with ZOLL® Defibrillators:

- ZOLL Defibrillators, such as;
- R Series
- M Series
- E Series

By Trained Personnel only, Including:

- Physicians
- Nurses
- Paramedics
- Emergency Medical Technicians
- Cardiovascular Laboratory Technicians

The OneStep Pediatric Electrodes are indicated for use on a patient less than 8 years of age or weighs less than 55 Lbs. (25Kg).

Comparison of Technological Characteristics:

The intended use of the OneStep Pediatric Multi-Function Electrodes as described in the indications for use, and labeling, has not changed as a result of this submission. For the ZOLL R Series, M Series and E Series, the connection to the defibrillator cable is identical to the predicate devices. All four products use the same hydrogel, adhesive material and have a conductive area similar in size that meet/exceed National and International Standards ANSI/AAMI DF80 and EN 60601-2-4 respectively.

Nonclinical Testing:

The OneStep Pediatric Electrode System has been subjected to extensive performance testing to ensure the device meets all of its functional requirements and performance specifications as defined in applicable National/International recognized standards.

Validation Project Number (VPN) 0731 addresses design validation to ensure the safety and effectiveness considerations have been successful in integrating the OneStep electrode with previously stated ZOLL defibrillators and performs as well and/or better than the legally marketed predicate devices. Applicable standards are defined in Form FDA 3514, VPN 0731 and Section 2, Device Description, within this premarket submission.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room –WO66-G609  
Silver Spring, MD 20993-0002

Zoll Medical Corporation  
c/o Mr. Robert Morse  
Director, Regulatory Affairs  
Bio-Detek, Inc.  
525 Narragansett Park Drive  
Pawtucket, RI 02861

MAY 13 2011

Re: K110978  
Trade/Device Name: OneStep Pediatric Multi-function Electrode  
Regulation Number: 21 CFR 870.5310  
Regulation Name: Automated External Defibrillator  
Regulatory Class: Class III  
Product Code: MKJ, DRO, DQA, LDD, LIX  
Dated: April 6, 2011  
Received: April 7, 2011

Dear Mr. Morse:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

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Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) number (if known): K110978

Device Name: OneStep™ Pediatric Multi-Function Electrode

Intended Use:

- Defibrillation
- Cardioversion
- Noninvasive Pacing
- ECG Monitoring

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(Please do not write below this line – Continue on another page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K110978

Prescription Use ☒

OR

Over the Counter Use ☐

(Per 21 CFR 801.109)

Rev. 1